

**Notice of Allowability**

Application No.

10/826,538

Examiner

Taylor Victor Oh

Applicant(s)

REDKAR ET AL

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/8/05.
2. ☒ The allowed claim(s) is/are 1-12.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 7/15/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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The previous final rejection has been vacated; the amendment after the final rejection filed on 7/08/05 will be entered.

The Status of Claims

Claims 1-12 are pending.

Claims 1-12 have been allowable.

Examiner's Amendment and Reasons of Allowance

I. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with an attorney of record, Jack Matalon on 7/15/05.

II. The application has been amended as follows:

In claim 1 on page 2 (amendment filed on 7/8/05):

The term "--75--" after the term "about" has been replaced with the number "80".

III. The following is an examiner's statement of reasons for allowance:

- The close references for the current invention are  
Chopdekar et al (U.S. 5,663,415) , Gordziel (U.S.  
6,287,597) and Sikora et al(U.S. 6,268,012).

Chopdekar et al discloses a process of preparing antihistamine tannates ; for example , diphenhydramine tannate can be obtained from reacting an antihistamine selected from the group consisting of diphenhydramine, phenylephrine, pyrilamine, and etc. with tannic acid at the reaction temperature of 65 to 70<sup>0</sup> C in the presence of water (50 wt %) for a period of time in the range of 5 minutes to 4 hours, thereby obtaining the resultant product with 2 wt % of water at a reduced pressure or under vacuum at a temperature of 60<sup>0</sup> C.

Gordziel teaches a process of preparing antihistaminic/decongestant tannate compositions , such as pyrilamine tannate, and phenylephrine tannate by reacting an antihistamine free base , such as pyrilamine and phenylephrine, with tannic acid in the presence of a solvent ; Gordziel , also, has offered guidance that the compositions can be used for oral administration in the form of tablets, suspensions, and powders.

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Furthermore, Sikora et al teaches a generic process for dehydrating pharmaceutical compounds by using the drying medium containing nitrogen.

The instant invention, however, differs from the prior art in that Chopdekar's declaration has shown that the claimed invention possessed unexpected results regarding the drying time and total processing cost in comparison with the primary Chopdekar et al as shown below:

	<u>Hot-Melt Process</u>	<u>Freeze-Dry Process</u>
Reaction Time	2 hours	2 hours
Reaction Temp., °C	85-90	65-70
Free Water, wt. %	10	50
Drying Time, hours	8	108
Total Processing Cost, \$/kg	23.89	194.67

Therefore, the claimed invention would not have been obvious to the person with an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.

Any inquiry concerning the communication after allowance such as sending all post-allowance correspondence should be directed to "Box Issue Fee" or faxed directly to PUBS at 703-305-8755. This will expedite the process of these papers.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Aug 11/05*

*Cecilia Tsang*

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